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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 976,617	10 12 2001	Chad A. Murkin	00-713-124	2303

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EXAMINER

RILEY, JEZIA

ARTICLE	PAPER NUMBER
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1637

DATE MAILED: 02 26 2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/976,617

Applicant(s)

MIRKIN ET AL.

Examiner

Jezia Riley

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 425-430 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 425-430 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 425-430 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engelhardt et al. (5,288,609) in view of Brooks et al. (5,571,726).

Engelhardt provides methods for the detection of genetic material such as DNA or RNA. The methods are based upon techniques which utilize two single stranded polynucleotide segments, with each segment comprising a label. Each single stranded polynucleotide segment is complementary to the same or the opposite strand of the target genetic material. When two single stranded polynucleotide segments are

separate segments, there are two polynucleotide probes and when the two single stranded polynucleotide segments are part of the same polynucleotide segment there is one polynucleotide probe, albeit such one polynucleotide probe comprises two single stranded polynucleotide segments of interest. Thus, when the method is carried out, a double hybrid is formed which comprises two polynucleotide probes joined by their hybridization to the target genetic material (hereinafter referred to as the "double hybrid"). Also, depending upon the choice of label and whether or not the two single stranded polynucleotide segments are separate polynucleotide segments or are part of the same polynucleotide segment, the double hybrid can be interconnected so as to form a multihybrid (hereinafter referred to as the "multihybrid"). Both the double hybrid and the multihybrid are detectable.

Brooks et al. relates to a chemical coupling process whereby colloidal metal particles, in particular colloidal gold sols, can be attached to specific binding proteins or immunochemically reactive components. These immunochemically reactive components include DNA and RNA nucleotide sequences, including recombinant oligonucleotide sequences. This unique coupling process allows the immunochemically reactive component to be attached to the surface of the colloidal gold particles with retention of much of the original reactivity. These colloidal gold particles thus labelled with the specific immunochemically reactive component are used as specific reagents in multiple immunoassay detection systems.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use gold particles for the method of Engelhardt. An important advantage is provided in that this chemical coupling process enhances the stability of these colloidal gold reagents and it allows them to function effectively in concert with a wide variety of stringent immunoassay conditions. As probes, gold particles are particularly interesting because their electron dense properties allow detection by transmission electron microscopy (TEM), their capability of strong emission of secondary electrons allows visualization by scanning electron microscopy (SEM), their characteristic X-ray signals allow identification of gold markers on cell surfaces. In addition, gold probes are also useful in fluorescent microscopy by labelling gold particles with fluorescent molecules. Gold particles bound to a cell surface appear as an orange-red coating and are therefore useful in photonic microscopy and in macroscopic observations.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 425-430 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 425-430 are vague and indefinite because they depend from canceled claims 237-265.

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### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 425-430 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 433-436, 446-448, 458-461, of copending Application No. 09/975,498. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming the same methods but of different scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

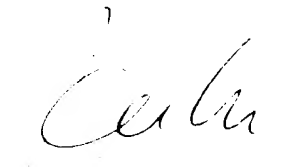
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855.

The examiner can normally be reached on 9:30AM - 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
**JEZIA RILEY**  
**PRIMARY EXAMINER**

February 22, 2003